

4/19/99

K990159

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## 510(K) SUMMARY

**SUBMITTER:** Yaw C. Yang, Ph.D.  
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**DATE** Jan./11/1999  
**PREPARED:**

**DEVICE NAME :** DYNAMIC Hollow Fiber Dialyzer DH-Series

**PREDICATE** Focus R-Series Hollow Fiber Dialyzers  
**DEVICE :** Gambro GFS plus Series Hemodialyzer  
Dynamic Hollow Fiber Dialyzer DC-series

### Device Description

Blood enters a blood inlet port where it is distributed to hollow fibers. Each hollow fiber has an inner diameter of 200 microns and a wall thickness of 8 microns. The fibers used in this device which is substantially equivalent to the fibers utilized in the Focus R-Series Hollow Fiber Dialyzers (K914790) and Gambro GFS plus Series Hemodialyzer (K902481), which have been previously approved under a 510(k) Notification. The wall thickness of the hollow fibers in Focus R-Series Hollow Fiber Dialyzers and the proposed device is 8 microns. The inner diameter of hollow fibers in both Focus R-Series Hollow Fiber Dialyzers, Gambro GFS plus Series Hemodialyzer and the proposed device is 200 microns. The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port.

## Predicate Devices

The DYNAMIC Hollow Fiber Dialyzer DH-Series Dialyzers are substantially equivalent in construction, design, intended use, and function to other hemodialyzers currently marketed in the United States. The DYNAMIC Hollow Fiber Dialyzer DH-Series Dialyzers are substantially equivalent in function, design, and operation to the Focus R-Series Hollow Fiber Dialyzers , Gambro GFS plus Series Hemodialyzer, and DYNAMIC Hollow Fiber Dialyzer DC-Series(K973291), which have been previously approved for marketing in the United States under 510(K) Notifications.

## Intended Use

The DYNAMIC Hollow Fiber Dialyzer DH-Series are indicated for use whenever a patient is in acute or chronic renal failure and hemodialysis is prescribed by a physician. Therefore, use of the device should be only on direction of a physician who has evaluated all of the aspects of the patient's illness. The indication statement is essentially the same as the indication statement of the predicate devices.

## Technological Characteristics

Comparing the proposed device to the predicate devices, similarities are noted in the design and materials employed to accomplish the same intended use. All of the proposed device , Gambro GFS plus Series Hemodialyzer, and DYNAMIC Hollow Fiber Dialyzer DC-Series utilize polycarbonate for the header material and polyurethane for the membrane potting material. The proposed devices, Focus R-Series Hollow Fiber Dialyzers, and DYNAMIC Hollow Fiber Dialyzer DC-Series are sterilized by ethylene oxide gas.

## In Vitro Performance

In vitro testing was performed on the proposed device to

determine the following: urea, creatinine, phosphate, and vitamin B12 clearances, and ultrafiltration coefficient. The result indicates that the proposed device is substantially equivalent to Focus R-Series Hollow Fiber Dialyzers 120H-R(K914790) , Gambro GFS plus 20 Hemodialyzer (K902481), and DYNAMIC Hollow Fiber Dialyzer DC-Series (K973291) for in vitro performance.

## Conclusions

Testing performed on the DYNAMIC Hollow Fiber DH-Series indicated that it is safe, effective, and performs as well as the predicate devices, when used in accordance with the instructions for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 19 1999

Yaw C. Yang, Ph.D.  
President & CEO  
DYNAMIC TECHNOLOGY CORP.  
2F, No. 53, Park Ave. II  
Science-Based Industrial Park  
Hsinchu, TAIWAN, R.O.C.

Re: K990159  
DYNAMIC Hollow Fiber Dialyzer DH-Series  
Dated: January 11, 1999  
Received: January 19, 1999  
Regulatory Class: II  
21 CFR 876.5820/Procode: 78 FJI

Dear Dr. Yang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K990159

Device Name: DYNAMIC Hollow Fiber Dialyzer DH-Series

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

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Concurrence of CDRH, Office Device Evaluation (ODE)

David A. Segura  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K990159

Prescription Use ✓ OR Over-The -Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)